Compliance Assistance Tool for Clean Air Act Regulations: Subpart GGG of40 CFR NESHAPS for Source Category Pharmaceutical Production

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Chapter 8
Initial Compliance Demonstrations and Testing Procedures

8.1 Overview

The MACT regulations require that affected sources provide proof that the facility is in initial compliance with the standards. The exact format of the initial compliance demonstration depends on the nature of the source and the regulatory standard option chosen by the owner or operator. In some cases, performance testing of the control devices will be necessary; in others, engineering calculations can be used to demonstrate that the emissions will be controlled to the required level.

Because the owner or operator has flexibilities or options, with regard to the regulatory standard chosen, he/she must develop a strategy that best suits the facility. It is important to remember that the pharmaceutical MACT is process-based. This means that the standards apply to a process (a group of steps that result in the production of a product or isolated intermediate), rather than a particular piece of equipment.

Other than the Alternative Standard, the initial compliance demonstration will also be used to establish monitoring parameter levels, as necessary. For example, during the initial compliance performance test, the O/O will establish control device and/or process monitoring parameter levels to be used to demonstrate on-going compliance. Details of this procedure will be discussed in Chapter 9.

Chapter 8 at a Glance

What are the Elements of a Compliance Strategy?

For the pharmaceutical manufacturing operations, the owner or operator should develop a compliance strategy, considering at least the following elements:

- Identification of PMPUs,
- Emission sources within each PMPU,
- The associated standards for those

PMPUs,
- Control options for emissions standards
- The associated compliance demonstration procedures for the standards, and
- The associated monitoring requirements.

The owner or operator may need to ask some questions relating to the overall facility, such as:

How often do the processes change and how will this affect the choice of standards and compliance demonstrations?

Which emission episodes will be controlled by which control device and to what level?

Will it make sense to vent numerous process streams to one centralized control device?

Would additional costs incurred in reconfiguring to a centralized control device be offset by a reduction in compliance demonstration and monitoring costs?

Are there pollution prevention technologies that could be applied instead of using traditional end-of-pipe controls ?

8.2 Structure of the Regulation

Compliance demonstration requirements are listed in §63.1257 for the following categories:

§63.1257(a)	General Requirements
§63.1257(b)	Methods
§63.1257(c)	Storage Tanks
§63.1257(d)	Process Vents
§63.1257(e)	Wastewater Sources
§63.1257(f)	Pollution Prevention *
§63.1257(g)	Compliance w/ Storage Tank Provisions by Using Emissions Averaging**
§63.1257(h)	Compliance with Process Vent Provisions by Using Emissions Averaging**

* Compliance information for this section is covered in Chapter 10.
** Compliance information for these sections is covered in Chapter 11.

8.3 Exemptions from Compliance Demonstrations

No initial compliance demonstration is required if the following devices are used to control emissions:

- a boiler or process heater with a design heat input capacity of 44 megawatts or greater,
- a boiler or process heater in which the emission stream is introduced with the primary fuel,
- a boiler or process heater that burns hazardous waste and which is either permitted under RCRA and in compliance with Part 266, Subpart H (Hazardous Waste Burned in Boilers and Industrial Furnaces) or has certified compliance with the interim status requirements of Part 266, Subpart H,
- a hazardous waste incinerator that is either permitted under RCRA and in compliance with Part 264, Subpart O (Incinerators) or has certified compliance with the interim status requirements of Part 265, Subpart O.

A compliance demonstration, per se, is not required when the alternative standard is being used. The owner/operator must be in compliance with the applicable monitoring requirements (63.1258 (b)(5)) on the initial compliance date.

8.4 Compliance Demonstration Procedures - Summary

Table 8-1 details which kinds of compliance demonstrations are required for each type of emission source - process vents, storage tanks,
and wastewater, assuming that the owner or operator is not using one of the control devices listed above that are exempt from compliance demonstrations.

NOTE: Separate compliance demonstrations are not required for storage tanks if their emissions are routed to control devices which have met the process vent compliance demonstration.

Before the comprehensive table of compliance demonstration requirements by source type is reviewed (Table 8-1), it may be helpful to gain an understanding of some of the terms used in the regulations for types of demonstrations:

Type of Demonstration	Plain English Definition
Emissions Estimation Methods	Using a **set of equations provided by EPA (or other validated equations)** in the rule to calculate emissions for process vents from **eight specific activities -** vapor displacement, purging, heating, depressurization, vacuum systems, gas evolution, air drying, and empty vessel purging.
Engineering Assessments	Using **other methods** (e.g., data from previous emissions tests) to calculate emissions primarily from **activities other than the eight listed above**. Engineering assessments <u>can</u> be used to calculate emissions from those eight activities <u>if</u> the emissions estimations equations aren't accurate or appropriate for the specific process. (NOTE: Must be approved by EPA)
Design Evaluation	Using control device **manufacturer's specifications** and other relevant site-specific data to show that the device will achieve the required efficiency.
Performance Testing	Designing and conducting **test runs of the process** to demonstrate that required emission reductions are achieved. Conditions under which testing was conducted must be carefully documented. Owners/operators must use EPA-specified test methods unless the source has petitioned and gained approval to use an alternative test method.

Condensers

Finally, before the table is reviewed, it should be understood that **if a condenser is used as the control device**, the owner/operator **must use the emissions estimations procedures** to demonstrate compliance at a measured temperature.

If the condenser is used as a process condenser, the owner/operator must initially demonstrate that the condenser is properly operated if:

- - the process condenser is not followed by an APCD, or
- - the APCD following the process condenser is not a condenser or is not meeting the 20 ppmv TOC

alternative standard (50 ppmv, if non-combustion device).

The owner or operator must either:

1. Show that the condenser exhaust gas temperature is less than the boiling or bubble point of the vessel contents, or
2. Perform a material balance around the vessel and condenser to show that at least 99 percent of the material that vaporizes is condensed.

This initial demonstration must be done for all appropriate operating scenarios and documented in the Notification of Compliance report.

Each kind of compliance demonstration is indicated with a bold number in Table 8-1 below.

Table 8-1. INITIAL COMPLIANCE DEMONSTRATION TECHNIQUES

Source	Regulatory Standard or Criteria	Type of Compliance Demonstration
Storage Tanks	Percent reduction	**Ú** Design evaluation or **Ü** Performance testing (note: testing not required if device also controls emissions from process vents and compliance has been demonstrated under process vent provisions.
	Alternative standard **-** 20 ppmv TOC if combustion, 50 ppmv if noncombustion	**Þ** TOC Monitoring at outlet of control device. Monitor must meet Performance Specification 8 (QA and calibration for CEMs) or 9 (QA and calibration for GC analysis) of Part 60, Appendix B. Use Method 18 to determine predominant HAP, if monitor is calibrated on predominant HAP.
	floating roof	**HON demonstration -** Refer to HON Inspection Tool **-** EPA 305-B-97-006, September, 1997 for guidance on engineering specifications in §63.119 (b)–(d) and monitoring in §63.120.
	vapor balancing	Information from reloading/cleaning facility (see page 8-25)
Wastewater Effluent	applicability criteria (PSHAP and SHAP conc. and loading) (alternatively, may designate as affected)	**ß** calculation of **annual average concentrations** and **annual load,** using EPA-approved methods, previous knowledge of wastewater, or bench-scale/pilot-scale test data
	wastewater treatment unit standards **-** percent removal or specific concentration of PSHAP or SHAP in ppmw	**RCRA units (with RCRA permit or interim status)** or **enhanced biological treatment meeting definition in §63.1251 - no demonstration required under this subpart**. **Non-biological or closed biological**: **à** Wastewater treatment performance testing, or **á** Wastewater design evaluation **Open biological**: **à** Wastewater treatment performance testing

Source	Regulatory Standard or Criteria	Type of Compliance Demonstration
Wastewater Air Emissions	air pollution control device standards - percent reduction	Ü Performance testing, or á Wastewater design evaluation
	Outlet TOC standard - 20 ppm TOC	Ú Design evaluation or testing using Method 25A
Process Vents	Mass emission limit	**Determine uncontrolled HAP**: Use either: Ø Emission estimation methods, (for vapor displacement, purging, heating, depressurization, vacuum systems, gas evolution, air drying, and empty vessel purging) or Ù Engineering assessments (for operations other than those listed above). AND **Determine controlled emissions**: For <u>small devices</u> controlling less than 10 TPY HAP, use: Ú Design evaluation (except for condensers), or Û Emission estimation methods (condensers only), or Ü Performance testing. For <u>large devices</u> controlling 10 TPY or more, use: Û Emission estimation methods (condensers only), or Ü Performance testing, or Ý Previous performance test performed under conditions required by §63.12.
	Percent reduction	Ü Performance testing, or **Determine uncontrolled HAP**: Use either: Ø Emission estimation methods (for vapor displacement, purging, heating, depressurization, vacuum systems, gas evolution, air drying, and empty vessel purging), or Ù Engineering assessments (for operations other than those listed above or where the owner/operator has demonstrated that the equations are not appropriate), AND **Determine controlled emissions**: For <u>small devices</u> controlling less than 10 TPY HAP, use: Ú Design evaluation (except for condensers), or Û Emission estimation methods (condensers only), or Ü Performance testing. For <u>large devices</u> controlling 10 TPY or more, use: Û Emission estimation methods (condensers only), or Ü Performance testing, or Ý Previous performance test performed under conditions required by §63.12.

Source	Regulatory Standard or Criteria	Type of Compliance Demonstration
	Outlet TOC standard - 20 ppm TOC	Ú Design evaluation or testing using Method 25A
	Alternative TOC Standard (20 ppmv if combustion, 50 ppmv if non-combustion)	Þ TOC Monitoring at outlet of control device. Monitor must meet Performance Specification 8 (QA and calibration for CEMs) or 9 (QA and calibration for GC analysis) of Part 60, Appendix B. Use Method 18 to determine predominant HAP, if monitor is calibrated on predominant HAP.

A general discussion of compliance demonstration procedures for each source type is presented in Sections 8.5 - 8.7. Each type of compliance demonstration procedure will be discussed by referencing the numbering system used in the above table.

8.5 Compliance Demonstration Procedures for Process Vents

Compliance demonstration procedures for process vents are listed in §63.1257(d). Procedures are given to demonstrate compliance with the following types of standards:

- Mass emissions limit
- Percent reduction or outlet TOC concentration
- Alternative standard

To determine mass emission rates and percent reductions, the rule provides compliance demonstration procedures for calculating uncontrolled emissions and controlled emissions. A further breakdown of these techniques is given in Figure 8-1a (uncontrolled emissions) and Figure 8-1b (controlled emissions). Uncontrolled emission rates from vents are calculated using ***emission estimations*** (equations provided for eight specified operations that produce emissions) or ***engineering assessment*** procedures (for emissions events other than the eight specified or for emission events not accurately represented by the emission estimation equations). Controlled emission rates are determined by ***design evaluations***, ***emission estimation*** or ***performance testing***.

NOTE: For control devices, except for condensers, controlling sources with HAP emissions at least 10 tpy (large device), performance testing must be used to determine controlled emissions (except for sources using the alternative standard option). Compliance with TOC standards is demonstrated using parametric monitoring when monitoring TOC as a surrogate for percent reduction and TOC CEM monitoring when monitoring TOC for the alternative standard. Þ

What are the Emission Estimation Procedures for Calculating Uncontrolled Emissions for Process Vents?

Equations are provided to calculate uncontrolled emissions from process vents for the following emission episodes types:

C Vapor Displacement

- Purging
- Heating
- Depressurization
- Vacuum Systems
- Gas Evolution
- Air Drying
- Empty Vessel Purging

These equations are listed in §63.1257(d)(2)(I) A through H, respectively. Basic chemical engineering principles are used to calculate mass rates of HAPs. Appendix EE to this tool provides a listing of the equations and equation inputs.

Equations from the 1978 document “Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products,” EPA - 450/2-78-029 (CTG) and equations from the 1994 ACT are included in the rule.

Other equations, as approved by EPA, may be used for emissions estimations.

Figure 8-1a provides a flow diagram illustrating the determination of uncontrolled emissions from process vents. Figure 8-1b shows the determination of controlled emissions.

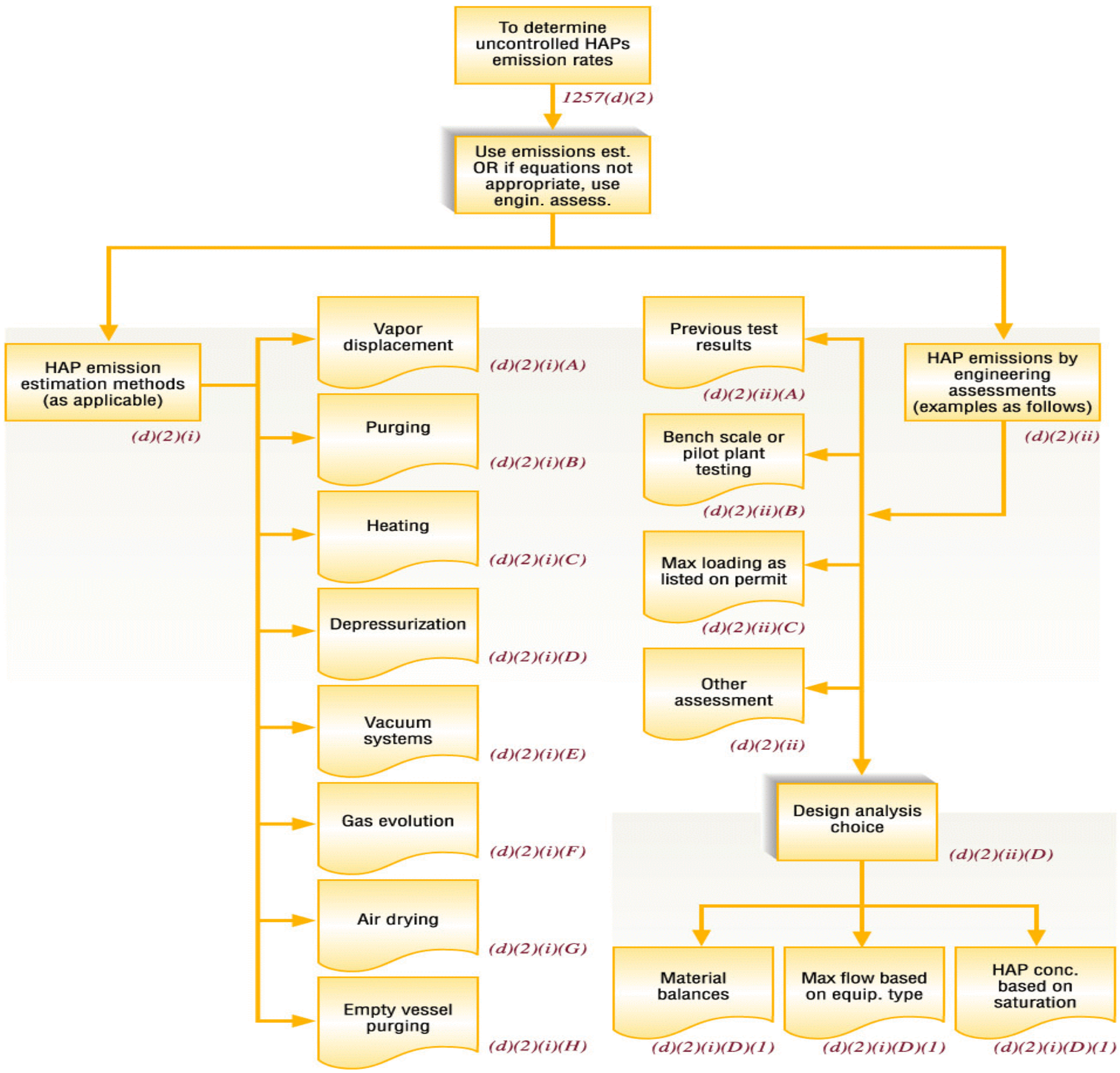

Figure 8.1a. Determining Uncontrolled Emissions from Process Vents

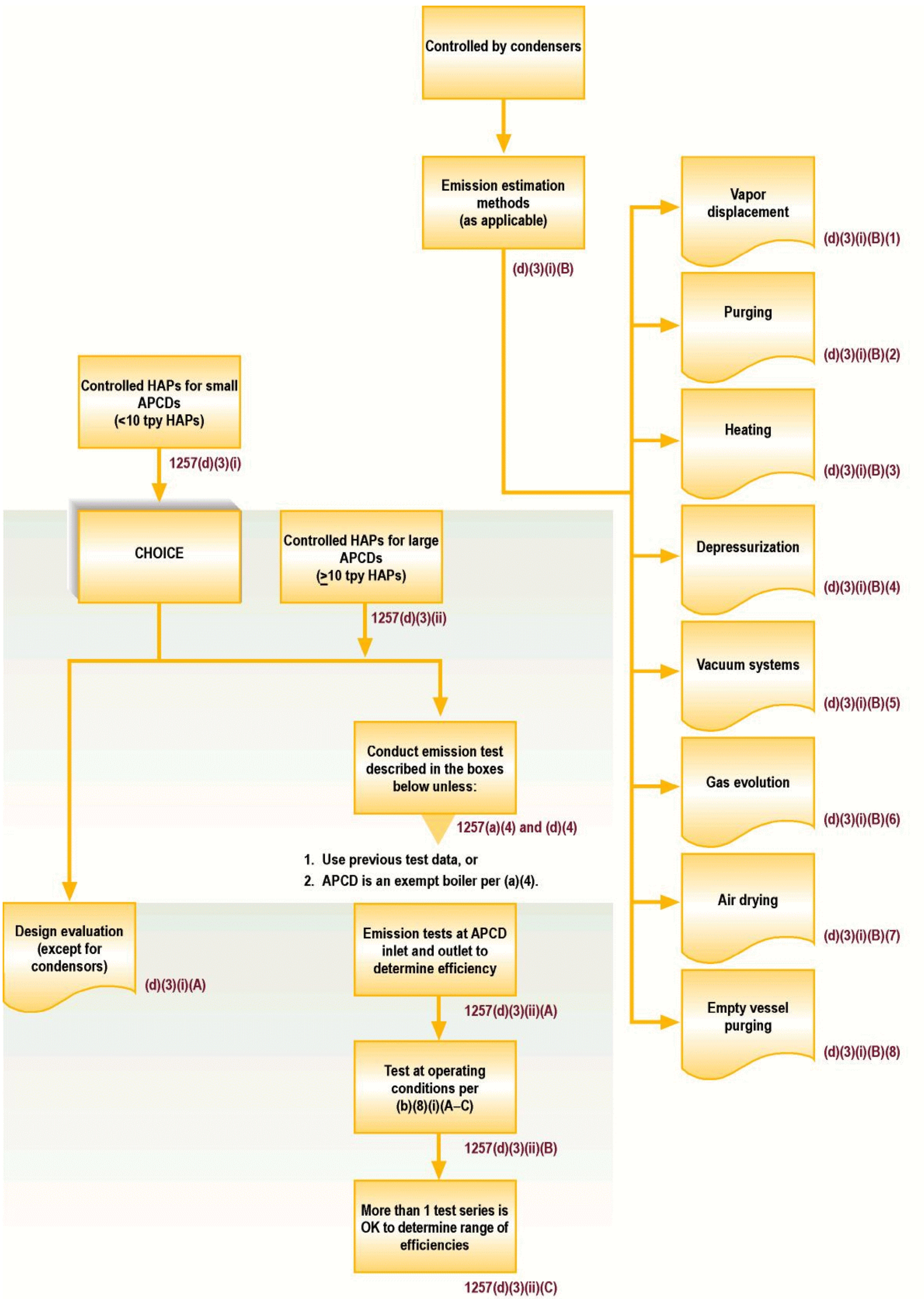

Figure 8-1b. Determining Controlled Emissions from Process Vents

What are the Engineering Assessments for Calculating Uncontrolled Emissions for Process Vents?

Engineering assessments are used primarily to calculate uncontrolled process vent emissions for emissions episodes that are NOT due to any of the activities described above under emissions estimations (i.e., vapor displacement, purging, heating, depressurization, vacuum operations, gas evolution, air drying, or empty vessel purging). Engineering assessments can also be used to calculate uncontrolled emissions for those 8 specific activities if the owner/operator believes the equations are not accurate or appropriate for his/her facility; the Administrator must approve such use of engineering assessments. In addition, modified versions of the emissions estimations methods under Section 63.1257 (d)(2)(ii) can be used if the owner/operator shows they have been used to meet other regulatory obligations and they do not affect applicability determinations or compliance determinations. Engineering assessments techniques are given below:

Engineering assessments can include...	Provided that...
Previous test data	**Tests are representative of current operating practices at the process unit.**
Bench-scale or pilot-scale test data	**Data are representative of the process under representative operating conditions.**
Maximum flow rate, HAP emission rate, concentration, or other relevant parameter	**Value is specified or implied within a permit limit applicable to the process vent.**
Design analysis based on accepted chemical engineering principles, measurable process parameters, or physical or chemical laws or properties (e.g., use of process stoichiometry to estimate maximum organic HAP concentrations, estimation of maximum flow rate based on physical equipment design such as pump or blower capacities, estimation of HAP concentrations based on saturation conditions.)	**All data, assumptions, and procedures used to support engineering assessments are documented.**

What are the Design Evaluation Techniques for Calculating Controlled Emissions for Process Vents?

The design evaluation must demonstrate how the control device being used achieves the needed percent reduction to comply with the rule. Design evaluations can be used for process vents ONLY if the control device controls less than 10 TPY (if $10 TPY, performance testing must be done unless control device is a condenser).

As shown in Figure 8-2, for each type of control device, EPA specifies what factors must be considered in conducting the design evaluation and what operating parameters must be established. Each design evaluation must consider the composition and concentration of all gases, vapors and liquids entering the control device.

For devices controlling process vents, the design evaluation must show compliance at absolute worst-case condition as determined from the emission profile (Information on conditions is provided later in this chapter). EPA's intent in requiring worst case conditions for testing is to document the reduction efficiency of the control device under the most challenging conditions. It is presumed that the device will work at least as well, and maybe better than, when conditions were at their worst. The emission profile should include the HAP loading rate in lb/hr and include all emissions episodes in a process that could contribute to the vent stack load. Production scheduling should be documented to ensure that all processes contributing to each vent are being considered.

What are the Emission Estimation Procedures for Calculating Controlled Emissions for Small Control Devices for Process Vents?

For small control devices, (controlling less than 10 tpy HAPs) equipped with a condenser operating as a control device, controlled emissions can be calculated using emission estimation equations. These techniques for the most part are similar to those previously discussed in uncontrolled emission estimation procedures with the exception that temperature values are those at the control device or receiver (condenser). A full presentation of equations and input variables is shown in Appendix EE.

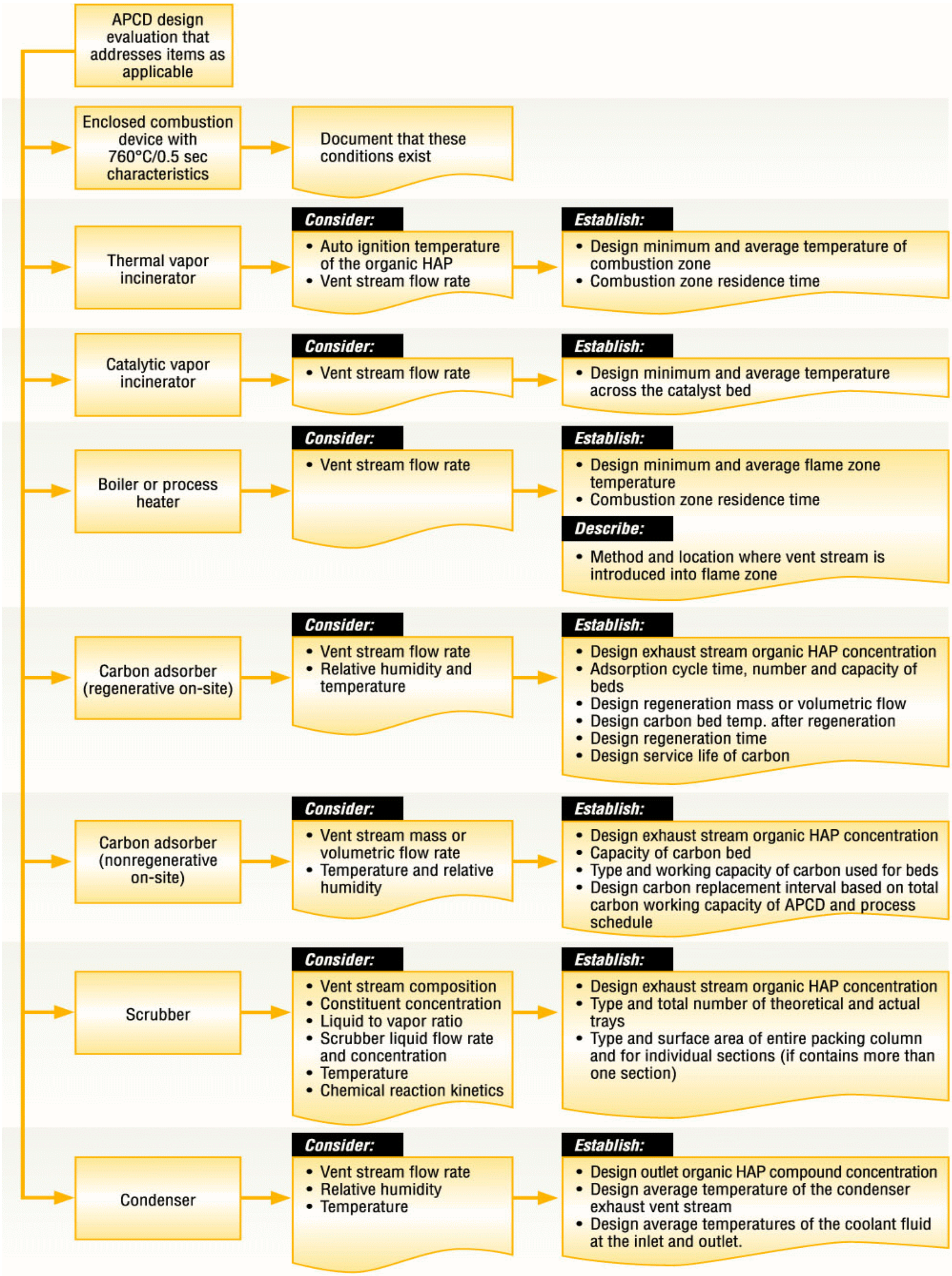

Figure 8-2. Emissions Control Device Design Evaluation Requirements

What is the Control Device Performance Testing for Process Vents?

Performance testing is required to demonstrate compliance for large control devices ($\geq$ 10 tpy HAPs). Previous test results may be used if the tests were conducted using the same procedures as provided by the rule at conditions typical of the appropriate worst case scenario. There are two primary objectives which must be considered in conducting performance tests:

- Demonstrate initial compliance, and
- Establish monitoring parameters for demonstrating on-going compliance.

Performance testing for demonstrating initial compliance can be broken down into the following tasks:

1. Test Plan Development and Submittal,
2. Testing, and
3. Report Writing and Submittal.

Test plans are to include the following information:

- Test program summary
    - List of sources to be tested
    - Test Methods
    - Test Conditions
- Test schedule
- Data quality objectives (precision, accuracy, and completeness of data)
- QA Programs - Internal (assessment of precision) and external (performance audits)

Further details on Performance testing are given in Appendix PT. Review the following Q and A boxes for more information on performance testing and emissions profiles.

Initial compliance demonstrations for condensers are based on how the condenser is used – as an air pollution control device or as a component of a process? For condensers used as APCDs: the owner/operator must determine controlled emissions by measuring exhaust gas temperatures and calculating emissions reduction for each batch emission episode within each unit operation. The owner/operator should use the equations for small devices for the eight specific procedures (vapor displacement, purging, heating, etc) or other approved equations, as discussed previously.

For condensers used as part of the process:

In configurations where the process condenser is not followed by an air pollution control device or the air pollution control device following the process condenser is not a condenser or is not meeting the alternative standard, the owner/operator must demonstrate that the process condenser is operating properly. This can be done by either:

1) measuring the exhaust gas temperature and showing that it is less than the boiling or bubble point of the substances in the vessel or

2) performing a material balance around the vessel and condenser to show that at least 99 percent of the material that vaporized during boiling is being condensed. The demonstration must be conducted for all appropriate operating scenarios. The owner/operator must document the results in the Notification of Compliance Report.

Q and A

Q. ***How do I demonstrate compliance with percent reduction standards?***

A. *The general equation for determining percent reduction requires the calculation of inlet and outlet mass rate of HAPs (or TOC) to the control device. Mass rate is calculated by multiplying HAP or TOC concentration by gas flow rate. As listed in Appendix PT, several test methods can be used for determining individual HAP concentrations, TOC concentration, and gas flow rate. However, each method has advantages and disadvantages and should be carefully reviewed before a selection is made.*

Q. ***What emissions test methods should be used?***

A. *Table 8-2 lists the emissions test methods to be used. These are taken from 40 CFR Part 60, Appendix A. Appendix PT describes these methods and discusses the advantages and disadvantages of each method.*

Q. ***Under what test conditions?***

A. *Test conditions for process vents, running in batch mode, should be at either absolute worst case or hypothetical worst case as defined in Table 8-3. These scenarios should be documented in an emissions profile. The owner or operator must prepare a site-specific test plan for approval 60 days prior to testing.* ***The test plan must include a description of proposed testing procedures as well as an emissions profile of the process.***

Testing storage tanks should be conducted during a reasonable maximum filling rate. Testing wastewater sources should be conducted under representative manufacturing process conditions and representative treatment operation.

Q, ***Do I need to determine uncontrolled emissions if I'm complying by using the outlet concentration standard or the Alternative Standard?***

A. *Yes, in the case of the outlet concentration standard. Uncontrolled emissions determination is needed to identify the worst case conditions for the performance test or design evaluation. It is* <u>not</u> *necessary to determine uncontrolled emissions if the Alternative Standard will be used because compliance is directly measured - no emissions profile is necessary.*

Table 8-2. EMISSIONS PERFORMANCE TEST METHODS

What's Being Measured	Method Number and Name (Appendix A of Part 60)
Sample and velocity traverse location	1 - Sample and Velocity Traverses for Stationary Sources OR 1A - Sample and Velocity traverses for stationary sources with small stacks or ducts
Velocity and volumetric flow rates	2 - Determination of stack gas velocity and volumetric flow rate (Type S pitot tube) OR 2A - Direct measurement of gas volume through pipes and small ducts OR 2C - Determination of stack gas velocity and volumetric flow rate in small stacks or ducts (standard pitot tube) OR 2D - Measurements of gas volumetric flow rates in small pipes and ducts
Gas analysis	3 - Gas analysis for carbon dioxide, oxygen, excess air, and dry molecular weight
Stack gas moisture	4 - Determination of moisture content in stack gases
HAP or TOC concentration *	25 - Total gaseous nonmethane organic emissions 26 or 26A - Determination of hydrogen chloride emissions, hydrogen halide and halogen from stationary sources 18 - Measurement of gaseous organic compound emissions by gas chromatography 25A - Determination of total gaseous organic concentration using a flame ionization analyzer. Can only be used for control efficiency determinations if any of the following conditions exist: 1. There is only one compound known to exist, 2. The organic compounds consist of only hydrogen and carbon, 3. Relative percentages of the compounds are known or can be determined and FID responses to the compounds are known, 4. A consistent mixture of the compounds exists both before and after the control device and only the relative concentrations are to be assessed, or The FID calibration gas used can be methane or the predominant HAP. The response from the high-level calibration gas must be at least 20 times the standard duration of the response from the zero calibration gas when the instrument is zeroed on the most sensitive scale. The span value of the analyzer must be less than 100 ppmv.

*** NOTE:** For determining speciated HAP concentrations, any method which has met EPA Method 301 validation criteria can also be used with the approval of the test administrator**.**

Q and A

Q. ***Who is the test administrator?***

A. *The test administrator is the regulator who has responsibility for approving the test plan, observing the tests, and accepting the test results. Typically, they are employees with the State or Local Air Pollution Agency who have jurisdiction over the facility through the issuance of air quality permits. In many cases, test objectives also include demonstrating compliance with air quality permit limits.*

Q. ***What should the emissions profile include?***

A. *The profile for the vent to the control device must describe the vent stream at the inlet to the control device under worst case conditions. The profile can be prepared using any one of the three following approaches:*

- ***By process:***
  - include all emission episodes contributing to vent stack load
  - describe scheduling that reflects all contributing processes
  - describe the HAP load to the device that equals the highest sum of emissions from the episodes that can vent to the control device in any given hour
  - use uncontrolled emissions calculations (emissions estimation equations or engineering assessments) to calculate emissions per episode. If the episode is longer than 1 hour, divide the emissions figure by the duration of the episode.
- ***By equipment:***
  - describe emissions that meet or exceed the highest emissions, in lb/hr, that would be expected under actual processing conditions
  - describe equipment configurations that yield the emission events described
  - include volatility of materials processed in the equipment
  - describe rationale used to identify and characterize the emissions (emissions may be based on a compound more volatile than compounds actually used in the process(es), and emissions may be generated from all equipment in the process(es) or only selected equipment.
- ***By capture and control device limitations:***
  - describe the highest emissions, in lb/hr, that can be routed to the control device, based on maximum flowrate and concentrations possible because of limitations on conveyance and control equipment.

In order to show that large control devices (handle at least 10 tons/yr) are achieving the required reduction efficiencies, performance tests must be performed at worst-case conditions.

The owner or operator can choose to use absolute worst-case or hypothetical worst-case, as defined below in Table 8-3**.**

Table 8-3. DEFINITIONS OF TYPES OF PERFORMANCE TEST CONDITIONS

Type of Condition	Definition
Absolute Worst-Case	If the **maximum load rate is the most challenging condition** for the control device, then absolute worst case equals: 1) period in which **inlet will contain at least 50 percent of the maximum HAP load** (in lb) capable of being vented to the device over any 8-hr period OR 2) period in which **inlet will contain the highest HAP mass loading rate** (in lb/hr) capable of being vented to the device **over a 1-hr period** If **condition other than maximum load rate is the most challenging condition** for the control device, then absolute worst case equals: The period of time when the **HAP loading or stream composition (including non-HAP) is the most challenging** for the control device (e.g., periods when stream contains the highest combined VOC and HAP load in lb/hr, periods when stream contains HAP constituents that approach limit of solubility for scrubbing media, periods when stream contains HAP constituents that approach limit of adsorptivity for carbon adsorption systems).
Hypothetical Worst-Case	**Simulated test conditions** that, at a minimum, contain the **highest total average hourly HAP load** of emissions that would be predicted to be vented to the control device, considering information included in the emissions profile.

Devising a Compliance Strategy
-An Example-

The example provided below shows how an emissions profile can be used to develop a compliance strategy for a specific process.

Table 1 lists the series of emissions events in Process A, starting with a methanol (MeOH) charge to the weigh tank. This table lists the uncontrolled and controlled emissions of one batch of the existing process prior to implementation of the MACT rule. Some emissions are controlled by condensers and/or a carbon adsorber. Some of the emissions are not currently routed to a control device. As shown at the bottom of the table, uncontrolled emissions for one batch are 673.01 pounds (methanol and chloroform). The overall control efficiency is 74.57%; controlled emissions are 171.18 pounds total. The owner/operator will need to determine whether it makes sense to comply with the 2,000 lb/yr limits standard or the 93% emission reduction standard.

Table 2 shows one possibility for a control strategy. First, the owner/operator should determine whether any vents are subject to the individual vent control requirement for 98% reduction. The table indicates that no individual vents have uncontrolled emissions greater than 50,000/year (25 tons/yr), so no vents are subject to the 98% requirement. In this case, after determining that no vents are subject to the 98% requirement, the owner/operator decides to attempt compliance with the 93% emissions reduction standard.

The gray boxes indicate where previously uncontrolled streams will be vented to the carbon adsorber. With a 90% reduction efficiency for methanol and a 95% reduction efficiency for chloroform, the new annual controlled emissions are listed in the column on the far right side of the table. As shown at the bottom of that column, the new overall control efficiency is 93.13%, which meets the MACT standard.

To demonstrate that the carbon bed will be able to achieve the standard, it must be tested at the maximum loading rate. Table 3 provides the emissions profile data for the carbon bed. In looking at the column labeled "Total HAP sent to CA (lb/hr)" it is clear that the maximum load occurs during the drying process, with 34.14 lb/hr sent to the carbon adsorber. This happens 123 hours into the batch. The owner/operator will conduct performance tests of the carbon adsorber during the dryer emissions event.

TABLE 1. COMPLIANCE STRATEGY

Process	Emission Event	Vent I.D.	Flowrate (scfm)	Duration (hr)	Processing Time (hr)	Pollutant	Uncontrolled Emissions (lb)	Control Device	Efficiency (%)	Controlled Emissions (lb)	Reference
A	MeOH Charge to Weigh Tank	WT-1	0.9	0.25	0.25	MEOH	0.14	None	NA	0.14	Calculations
A	Fermenter Charge and Purge	Ferm-1	133	12.25	12.5	MEOH	10	None	NA	10	Calculations
A	Ferm Mix Charge to Holding Tank	TK-1	2.21	1.2	13.7	MEOH	0.08	None	NA	0.08	Calculations
A	Extraction	EX-1	0.8	30	33.7	MEOH CHC13	1.2 185.5	Condenser Condenser	65.00% 58.00%	0.42 77.65	Calculations Calculations
A	Charge Organic Phase to Hold Tank	HT-2	0.64	1	34.7	MEOH CHC13	0.14 2.23	None None	NA NA	0.14 2.23	Calculations Calculations
A	Charge Aqueous Phase to Hold Tank	HT-3	2.5	1	34.7	MEOH	0.03	None	NA	0.03	Calculations
A	Strip Aqueous Phase	SS-1	0.1	3	37.7	MEOH	0.03	None	NA	0.03	Calculations
A	Charge to Concentrate Receiver	CR-1	0.03	20	57.7	MEOH CHC13	3.7 0.27	None None	NA NA	3.7 0.27	Calculations Calculations
A	Concentration of Organic	EVAP to CX	0.5	20	57.7	MEOH CHC13	9.1 123.9	Condensers and Carbon Condensers and Carbon	99.20% 99.40%	0.07 0.7	Calculations Calculations
A	Distillate Receiver from EVAP	DR-1 to CX	0.0003	20	57.7	MEOH CHC13	0.00039 0.013	Condensers and Carbon Condensers and Carbon	92.82% 99.62%	2.8E-05 5E-05	Calculations Calculations
A	Reactor Charge with Solvent	R-1 to CX	0.7	0.5	58.2	MEOH CHC13	0.16 2.14	Condensers and Carbon Condensers and Carbon	98.90% 99.30%	0.0017 0.016	Calculations Calculations
A	Reactor Heatup	R-1 to CX	6E-05	4	62.2	MEOH CHC13	0.07 0.97	Condensers and Carbon Condensers and Carbon	98.70% 99.20%	0.0009 0.008	Calculations Calculations
A	Distillate Receiver from R-1	DR-2	0.003	0.25	62.2	MEOH CHC13	0.0002 0.0006	None None	NA NA	0.0002 0.0006	Calculations Calculations
A	Centrifuge	CEN-1	1.7	2	64.2	MEOH CHC13	1.97 26.5	None None	NA NA	1.97 26.5	Calculations Calculations
A	Dryer	DRY-1 to CX	50	8	72.2	MEOH CHC13	25.06 247.5	Carbon Carbon	90.00% 95.00%	2.51 12.4	Design Evaluations Design Evaluations
A	Filtrate Receiver	FIL-1	0.17	5	69.2	MEOH CHC13	1.95 30.36	None None	NA NA	1.95 30.36	Mass Balance Calcs Mass Balance Calcs
					TOTAL:		673.01		74.57%	171.18	

TABLE 2. COMPLIANCE STRATEGY

Compliance Strategy		Emission Event	Vent I.D.	Flowrate (scfm)	Duration (hr)	Annual Uncontrolled Emissions (lb/yr)	Annual Controlled Emissions (lb/yr)	98% Control Required? (Y/N) (a)	Control vent to achieve overall 93% (Y/N) (b)	New Anuual Emissions (lb/yr) (c)
Batches/yr: 75		MeOH Charge to Weigh Tank	WT-1	0.9	0.25	10.50	10.50	N	N	10.50
Carbon Control Eff.		Fermenter Charge and Purge	Ferm-1	133	12.25	750.00	750.00	N	N	750.00
MeOH: 90.00% CHC13: 95.00%		Ferm Mix Charge to Holding Tank	TK-1	2.21	1.2	6.00	6.00	N	N	6.00
		Charge Organic Phase to Hold Tank		0.64	1	10.50 167.25	10.50 167.25	N N	N N	10.50 167.25
		Charge Aqueous Phase to Hold Tank		2.5	1	2.25	2.25	N	N	2.25
		Strip Aqueous Phase		0.1	3	2.25	2.25	N	N	2.25
		Charge to Concentrate Receiver		0.03	20	277.50 20.25	277.50 20.25	N	N	277.50 20.25
		Extraction		0.8	30	90.00 13,912.50	31.50 5,823.75	See below See below	Y (d) Y (d)	3.15 582.37
		Concentration of Organic		0.5	20	682.50 9,292.50	5.25 52.50	See below See below	Y Y	5.25 52.50
		Distillate Receiver from EVAP		0.0003	20	0.03 0.98	0.00 0.00	See below See below	Y Y	0.00 0.00
		Reactor Charge with Solvent		0.7	0.5	12.00 160.50	0.13 1.20	See below See below	Y Y	0.13 1.20
		Reactor Heatup		0.00006	4	5.25 72.75	0.07 0.60	See below See below	Y Y	0.07 0.60
		Centrifuge		1.7	2	147.75 1,987.50	147.75 1,987.50	See below See below	Y Y	14.77 198.75
		Dryer		50	8	1,879.50 18,562.50	188.25 930.00	See below See below	Y Y	188.25 930.00
		Filtrate Receiver		0.17	5	146.25 2,277.00	146.25 2,277.00	See below See below		14.62 227.70

Compliance Strategy		Emission Event	Vent I.D.	Flowrate (scfm)	Duration (hr)	Annual Uncontrolled Emissions (lb/yr)	Annual Controlled Emissions (lb/yr)	98% Control Required? (Y/N) (a)	Control vent to achieve overall 93% (Y/N) (b)	New Anuual Emissions (lb/yr) (c)
		Distillate Receiver from R-1		0.003	0.25	0.02 0.05	0.02 0.05	N N	N N	0.02 0.05
		TOTALS				50,476.06	12,838.31			3,465.94
										93.13%

Gray boxes: Not currently controlled or require additional control

(a) Whether or not these requirements apply to the vent is determined using the TRE equation.

(b) Which vents to control (in addition to the vents already controlled) to achieve an overall HAP reduction of 93 percent is a judgement call.

(c) New annual emissions estimated by routing streams not currently controlled or streams that require additional control to a carbon adsorber which achieves 90 and 95 percent reduction of methanol and chloroform, respectively.

(d) This stream is currently controlled by a condenser. In order to achieve the required 93 percent overall reduction of HAPs the outlet gas will be routed to a carbon adsorber.

TABLE 3. COMPLIANCE STRATEGY

Emission Event	Pollutant	HAP (lb/yr)	Total HAP LOADING (lb/yr) (a)	HAP (lb/batch) (b)	Duration (hr/batch)	Total HAP sent to CA (lb/hr)	Batch Time (hrs) (d)
MeOH Charge to Weigh Tank					0.25		0.25
Fermenter Charge and Purge					12.25		12.5
Ferm Mix Charge to Holding Tank					1.2		13.7
Extraction	MeOH CHC13	31.50 5,823.75	5855.25	78.07	30	2.60	43.7
Charge Organic Phase to Hold Tank					1		44.7
Charge Aqueous Phase to Hold Tank					1		45.7
Strip Aqueous Phase					3		48.7
Concentration of Organic	MeOH CHC13	53.10 1,053.75	1106.85	14.76	20	0.74	68.7
Charge to Concentrate Receiver					20		88.7
Distillate Receiver from EVAP	MeOH CHC13	0.02 0.08	0.101	0.00	20	0.00	108.7
Reactor Charge with Solvent	MeOH CHC13	1.30 23.40	24.7	0.33	0.5	0.66	109.2
Reactor Heatup	MeOH CHC13	0.64 11.52	12.16	0.16	4	0.041	113.2
Distillate Receiver from R-1	MeOH CHC13				0.25		113.45
Centrifuge	MeOH CHC13	147.75 1,987.50	2135.25	28.47	2	14.24	115.45
Dryer	MeOH CHC13	1,882.50 18,600.00	20482.5	273.10	8	34.14	123.45
Filtrate Receiver	MeOH CHC13	146.25 2,280.00	2426.25	32.35	5	6.47	128.45

(a) requires combining multiple HAPs from single emission episodes in order to estimate total HAP to the control device
(b) estimated on a batch basis by dividing the annual amount by the number of batches in a year (75)
(c) the emissions profile must include average HAP loading (lb/hr) versus time for all emission episodes routed to the device (d) the rolling batch duration was used to account for the entire length of the batch in the emissions profile

Q and A

Q. ***Why are there two types of testing conditions - absolute worst-case and hypothetical worst-case?***

A. *The EPA regulations allow the owner/operator the flexibility to define worst-case in terms of HAP load, HAP mass loading rate, or other factors relating to the operation of the control device. Hypothetical worst-case allows the owner/operator to simulate the worst-case conditions, in the event that it is very difficult to find a period when the device actually is under worst-case conditions without artificially staging the test and perhaps causing significant interruptions in production.*

Q. ***Are there any restrictions on my operation based on the type of performance test I conduct?***

A. *Yes; the owner or operator cannot operate the facility under conditions that are worse than the conditions under which the performance test was conducted. If "worst-case" conditions were properly identified in the test design, however, there should not be many, if any, instances where this occurs. Recall that a violation of an operating limit does not necessarily constitute a violation of an emission standard, except for condensers. In fact, the owner/operator may choose to preset multiple parameter levels to account for variation in batch emission streams. The owner/operator has the opportunity to review operating logs during periods of exceedances to determine if operating conditions are different from those under which the device was tested. If this is the case, and the owner/operator has preset multiple parameter levels to account for these variable periods, the exceedance will not count as a violation.*

What are Acceptable Previous Test Results?

Previous test results are acceptable for compliance demonstrations if they were:

- Performed using acceptable test methods (as listed in Table 8-2)
- Performed over conditions typical of appropriate worst case as listed in Table 8-3 for process vents, reasonable maximum filling rate for tanks, and representative <u>manufacturing process</u> operation and representative <u>wastewater treatment</u> operation for wastewater sources.

What are the TOC Alternative Standards & Outlet TOC Standards for Compliance Demonstration for Process Vents, Storage Tanks, and Wastewater Sources?

Total Organic Compounds, TOC, are measured as the sum concentration of all organic compounds in a gas stream. The rule makes reference to two TOC standards - the **Alternative Standard** and, for the sake of discussion here, the **Outlet TOC Standard**. A comparison is shown below in Table 8-4.

The **Outlet TOC Standard** can be considered a surrogate of demonstrating compliance with the percent reduction standard, because it allows an owner/operator to show initial compliance by measuring TOC. For demonstrating on-going compliance, the owner/operator can set operating parameters, or continue to monitor TOC directly with a CEM. The **Alternative Standard**, however, "locks" the owner/operator into monitoring TOC with a CEM for on-going compliance if the owner/operator continues to choose the alternative standard option for compliance.

Table 8-4. Comparison of the Alternative Standard and the Outlet TOC Standard

	Alternative Standard	**Outlet TOC standard**
Standard	for combustion control devices, $\leq$20 ppmv TOC and $\leq$20 ppmv hydrogen halides/halogens[1];	$\leq$20 ppmv TOC and $\leq$20 ppmv hydrogen halides/halogens
	for noncombustion, <50 ppmv TOC and <50 ppmv hydrogen halides/halogens	$\leq$ 50 ppmv TOC and < 50 ppmv hydrogen halides/HCl
Standard is an option for	**storage tanks and process vents**	wastewater streams and process vents
Standard applies to	**control device**	process vents or wastewater stream
Initial compliance demonstration requirements	Use a CEM to meet TOC and HCl monitoring requirements in §63.1258(b)(5) by the initial compliance date.[2]	Use methods in 63.1257(b) to demonstrate 20 ppmv TOC
Monitoring on-going compliance	Continue TOC monitoring and hydrogen halide and halogen every 15 minutes during operation	Meet monitoring requirements in §63.1258(b)(1)-(4). Owner/operator sets monitoring parameters (e.g., combustion temp.) during initial performance test.

1. In lieu of achieving the 20 ppmv outlet hydrogen halide and halogen concentrations the owner/operator may control post-combustion device HCL emissions by 95%.

2. When using a post-combustion control device to comply with the 95% HCl control efficiency option available under the alternative standard, the owner/operator may use methods in 63.1257(b) to demonstrate HCl compliance in lieu of a CEM.

NOTE: When a combustion device is used to comply with the outlet concentration standard, the actual TOC, organic HAP, and hydrogen halide and halogen must be corrected to 3 percent oxygen if supplemental gases are added to the vent stream or manifold. The applicable equation for calculating the corrected concentration is at 63.1257 (a)(3).

8.6 Compliance Demonstration Procedures for Storage Tanks

Compliance demonstration procedures for storage tanks are listed in 1257(c). Procedures are given to comply with the following types of standards:

- C Floating roof
- C Percent reduction
- C Alternative standard
- • Vapor balancing

To determine mass emission rates and percent reduction, compliance demonstrations are done by conducting ***design evaluations***, (see page 8-10) or ***performance testing*** (see page 8-12). Compliance with the TOC alternative standard is accomplished using ***TOC monitoring*** (see page 8-22). These methods are identical to those described in section **8.5** for process vents. Please note that design evaluations can be used for calculating controlled emissions from storage tanks regardless of the quantity of emissions controlled (i.e., there is no <10 TPY restriction). Floating roof demonstration requirements are listed in the HON, § 63.119(b-d) and §63.120(a-c). Because few pharmaceutical facilities use floating roofs, a detailed discussion is not included here. The reader is referred to the HON Inspection Tool (EPA - 305-B-97-006, September, 1997). The reader is referred to Appendix HON for more details. A separate compliance demonstration for tanks is not necessary for a storage tank if emissions are routed to a control device being used for process vents, and a compliance demonstration will be done in accordance with the process vent regulations.

If the owner or operator uses the vapor balancing option, the following requirements apply. Railcars or tank trucks that deliver HAPs to an affected source must be reloaded at a facility that either:
1) controls emissions via a closed vent system with a device that reduces inlet emissions of HAP by at least 90% or
2) controls emissions by using a vapor balancing system to route the collected HAP vapor back to the storage tank from which the material was originally transferred.

If option 1 is used to control emissions, the owner or operator needs to secure information from the reloading/cleaning facility that demonstrates compliance with the 90% reduction standard. Either performance testing or design evaluations can be done. If option 2 is used, the owner or operator must keep records that show what procedures will be followed when reloading and when displacing vapors back to the original storage tank. He/she must document each time the vapor balancing system is used to comply with the standard.

8.7 Initial Compliance Demonstration Procedures for Wastewater Sources

The initial compliance demonstration procedures as listed in §63.1257(e) are basically separated into 3 parts:

- Determination of wastewater HAP concentration and load as it pertains to wastewater applicability criteria,
- Design Evaluation and Performance Test procedures for demonstrating compliance with wastewater treatment standards, and
- Design Evaluation and Performance Test procedures for demonstrating compliance with APCD requirements.

The following discussion will address these three items.

How do I Calculate the Annual Average Concentrations and Load?

This calculation determines if a wastewater meets applicability criteria (four affected source categories), and should be performed using either:

C Analytical techniques listed in 63.1257(b) (10) i- iv . They are:
  - Method 305-Fm (Fm = Fraction measured = theoretical proportion in wastewater that volatilizes into air; as listed in Table 8 in the rule);
  - Methods 624, 625, 1624, 1625, 1666, or 1671;
  - Method 8270 or 8260;
  - Other EPA Methods validated using Method 301, 40 CFR 63 Appendix A, or "Alternative Validation Procedure for EPA Waste Methods" in 40 CFR 63 Appendix D; or
  - Non-EPA Method validated using Method 301, 40 CFR 63, Appendix A.

  (For any above techniques chosen, prepare a sampling plan documenting procedures for determining recovery efficiency of PSHAPs and SHAPs and incorporating similar sample handling requirements as Method 25D to ensure that losses of organic compounds during sampling are minimized.)

C Calculation techniques based on process wastewater knowledge, or

C Bench scale or Pilot scale test data.

NOTE: As discussed in Chapter 7, an o/o is exempted from performing wastewater characterizations for applicability determinations if he designates the wastewater stream as affected. If an o/o designates a wastestream as affected, he assumes the wastewater is subject to the standards, and therefore does not need to determine concentration and load annually. Designated streams are subject to the same standards as characterized streams. Wastewater treatment options are limited, however, and do not include treatment to 50 ppmw PSHAP or 520 ppmw SHAP, or using enhanced biological treatment.

How Do I Demonstrate Compliance With the Wastewater Treatment Standards?

If the owner or operator opts to use enhanced biotreatment or a RCRA-regulated unit, neither performance testing nor design evaluations are required. For any other non-biological treatment process, the owner or operator must do performance testing or a design evaluation. For closed biological treatment processes, either performance testing or design evaluations are required. For open biological treatment processes, performance testing is required.

Wastewater Treatment Performance Testing

Wastewater treatment performance testing procedures are given for the following types of treatment standards:

C wastewater concentration limits (noncombustion treatment)

C wastewater mass removal/destruction efficiency limits

Table 8-5 summarizes analytical methods for determining applicability and demonstrating initial compliance for wastewater.

Table 8-5. Summary of Analytical Methods for Wastewater Applicability and Initial Compliance Demonstrations

If you are measuring concentration to...	According to procedures specified in ...	Using...	Then...
Determine characteristics of an affected wastewater stream defined in §63.1256 (a)(1)(i)	§63.1257 (e)(1)	Method 305	Divide the measured concentrations by the appropriate compound-specific Fm factors before comparing the sum to the applicability threshold.
		Any other method, as described in §63.1257 (b)(10)(ii) through (v)	Compare the sum of the measured concentrations directly to the applicability threshold.
Demonstrate initial compliance with the outlet concentration limit in §63.1256 (g)(8)(i) or (9)(i)	§63.1257 (e)(2)(iii)(B)	Method 305	Compare the sum of the measured concentrations directly with the PSHAP and/or SHAP limits.
		Any other method, as described in §63.1257 (b)(10)(ii) through (v)	You may elect to multiply the measured concentrations by the appropriate compound-specific Fm factors before comparing with the PSHAP and/or SHAP limit.
Demonstrate initial compliance with any of the percent mass removal/destruction options in §63.1256 (g)(8)(ii), (9)(ii), (11), (12).	§63.1257 (e)(2)(iii(C) through (G)	Method 305	Divide the measured concentrations by the appropriate compound-specific Fm factors before using to calculate the mass flow rate
		Any other method, as described in §63.1257 (b)(10)(ii) through (v)	Use the measured concentrations directly to calculate the mass flow rates

*Method 305 = Measurement of Emissions Potential if Individual Volatile Organic Compounds in Waste

Q and A

Q. ***If I choose the sampling/analysis option for determining wastewater applicability characteristics, where do I sample and at what frequency and duration ?***

A. *The rule states that the samples must be collected either at the POD or downstream of the POD. If downstream, the resulting HAP concentrations must be corrected to reflect expected values which would occur at the POD. As for the sampling frequency and duration, the only guideline given is that the resulting SHAP/PSHAP concentration and load values are annual averages. In other words, the concentration must reflect the total mass of SHAP/PSHAP constituents delivered to the wastewater stream in a calendar year divided by the total mass of wastewater occurring in the same year. Sampling frequency and duration must be sufficient to calculate a representative average of these parameters. Once the applicability determination is made, it does not need to be revisited unless there are process changes that would change wastewater concentrations and/or loading such that applicability of the rule could change.*

Q and A

Q. ***How is the degradation factor (F_{bio}) calculated and used?***

A. *The degradation factor (F_{bio}) is calculated using the procedures found in Appendix C to Part 63 (Determination of the Fraction Biodegraded in a Biological Treatment Unit). Procedures are given for using F_{bio} in the following 3 biological treatment configurations:*

- *mass destruction/removal efficiency is determined across a biological treatment system only*
- *mass destruction/removal efficiency is determined across a series of treatment processes where the inlet to the equalization tank <u>can be</u> considered the biological treatment system inlet*
- *mass destruction/removal efficiency is determined across a series of treatment processes where the inlet to the equalization tank <u>cannot be</u> considered the biological treatment system inlet*

If hard piping is used to transport wastewater and the equalization tank has a fixed roof/closed vent system vented to an APCD, the inlet to the equalization tank can be considered the biological treatment system inlet. Also, in a general sense, if hard piping is not used to transport wastewater, total plant mass destruction/removal efficiency has to be calculated as the sum of individual treatment process removal efficiencies. Further details on wastewater treatment compliance are given in Appendix WWT.

Q. ***How do I demonstrate compliance for wastewater that is either treated off site or treated on site by a treatment facility not owned or operated by the source ?***

A. *The wastewater treatment plant O/O is responsible for the bulk of the demonstration procedure. However, the O/O of the wastewater source must perform the following:*

- *Demonstrate compliance with vapor suppression standards for all equipment used to transport wastewater prior to treatment, and*
- *Submit a notice to the treatment facility and keep a record for himself stating the wastewater contains organic HAP and must be treated in accordance with this rule. The notice must be submitted for each shipment, or if shipment is continuous, then an initial notice and whenever there is a change in the required treatment, and*
- *Additionally, though not required, it may be prudent for the owner/operator to:*

Verify that the treatment facility is certified to manage this waste in accordance with:

1. Wastewater treatment and emissions regulation of this rule, §63.1256 (b)-(i) (vapor suppression standards, emissions control device standards, wastewater treatment standards, and delay of repair standards), or

2. Subpart D of this part, if an alternative emissions limitation has been granted to the source in accordance with Subpart D (Regulations Governing Compliance Extensions for Early Reductions of HAPs), or

3. §63.6(g) - Use of an alternative non-opacity emission standard

Wastewater Treatment Design Evaluations

Wastewater treatment design evaluations can be used to demonstrate compliance for nonbiological and closed biological treatment systems. (If open biological treatment is being used, then performance testing must be performed to demonstrate compliance.) A wastewater design evaluation should be completed according to §63.1257(e)(2)(ii).

The following guidelines are given:

- Base the design evaluation on operation at a wastewater flow rate and a concentration under which it would be most difficult to demonstrate compliance, and
- For closed biological treatment processes, use a mass balance conducted over the entire unit, including any emission control devices, to determine mass removal/destruction rates.

Q and A

Q. How do I demonstrate initial compliance with vapor suppression standards?

A. There are few initial compliance demonstration requirements listed in the rule for vapor suppression standards. However, in the Reporting Requirements listed in § 63.1260(f), Requirements for Notification of Compliance Status Report, the report must include where appropriate, among other items, a list of monitoring devices, monitoring frequencies, and values of monitored parameters established during the initial compliance demonstrations. Therefore, the types of I & M procedures required for wastewater management units (i.e., vapor suppression inspection routines-discussed in Section 7.4 and in Table 9-3) must be established and documented at the time of the initial compliance demonstration period. Certain vapor collection systems, closed-vent systems, fixed roofs, covers, and enclosures must receive an initial inspection in accordance with Method 21 to determine whether there are any leaks (readings greater than 500 ppm above background), per 63.1260(h)(2)(i)(A). Vapor collection systems operating under negative pressure are not subject to this requirement. The reporting provisions in 63.1260(f)(2) require that the results of the inspection be submitted in the notification of compliance status report.

Note on choosing the biological demonstration procedure:

Closed Biological - If the O/O chooses closed biological treatment and demonstrates compliance using §63.1257(2)(iii)(E) or (F) (i.e., using a site-specific F_{bio}), then the treatment process is not subject to wastewater storage tank or surface impoundment vapor suppression standards.

Open Biological - If the O/O chooses open biological treatment, then the treatment process need not be covered and vented to a control device. As noted above, if compliance is being demonstrated by §63.1257(2)(iii)(E) or (F), the treatment process is not subject to wastewater storage tank or surface impoundment vapor suppression standards.

How Do I Demonstrate Compliance With the APCD Standards?

As with the wastewater treatment standards, the owner or operator must conduct performance testing or design evaluations to demonstrate that the air pollution control devices are operating efficiently and achieving the necessary control. The compliance demonstration requirements are summarized in Table 8-6.

Table 8-6. Compliance Demonstrations for APCDs used for Wastewater Sources

Compliance Demonstration for APCDs	Standard	Summary of Procedure
Performance Testing 63.1257(e)(3)(i)	95% reduction 20 ppmv outlet limit	Follow same general performance test procedures of 63.1257(e)(2)(iii)(A)(1)-(4): - demonstrate during representative process operating conditions - demonstrate during representative treatment process operating conditions - supplement perf. test results with modeling or engineering data, if necessary, to demonstrate performance over a range of conditions - sample at inlet and outlet of APCD - minimum of 3 1-hr test runs - Method 18 or other method validated via Method 301 - calculate concentration of TOC or total organic HAP (correct to 3% oxygen if combustion device) - calculate mass rate - compare mass destruction efficiency to 95% standard or compare outlet concentration to 20 ppmv standard
Design Evaluation	95% reduction or 20 ppmv outlet limit	Follow design evaluation requirements as described on page 8-10 and 8-11 of this chapter
Flare Demonstration 63.1257(e)(3)(iii)	Flare	Operate flare as provided under 63.11; no performance testing or TOC testing required for demonstration

Note: no compliance demonstration is necessary if APCD is a boiler or process heater with design heat input capacity of 44 megawatts or greater, a boiler or process heater in which the emission stream is burned with the primary fuel, or a RCRA-regulated unit.

8.8 Submittal of Compliance Demonstrations for All Affected Sources

The O/O must submit supporting data and analyses used in compliance demonstrations in either the Precompliance Report or in the Notice of Compliance Status Report, depending on the nature of the information being submitted. The following information must be included:

Table 8-7. COMPLIANCE DEMONSTRATION PLANS AND REPORTS

Precompliance Report	Notice of Compliance Status Report
Submit at least 6 months prior to compliance date	Submit no later than 150 days after the compliance date
Include**:** **Data and rationale** used to support an engineering assessment to calculate uncontrolled emissions from process vents **Data and information** used to support determination of annual average concentration in wastewater by process simulation**.** **Bench or pilot data** used to determine annual average concentration in wastewater**.**	Include: (1) The results of any **applicability determinations, emission calculations, or analyses used to identify and quantify HAP emissions** from applicable sources. (2) The results of **emissions profiles, performance tests, engineering analyses, design evaluations, or calculations used to demonstrate compliance.** For performance tests, results should include descriptions of sampling and analysis procedures and quality assurance procedures. (3) **Descriptions of monitoring devices, monitoring frequencies, and the values of monitored parameters** established during the initial compliance determinations, including data and calculations to support the levels established. (4) **Operating scenarios**. (5) **Descriptions of worst-case operating and/or testing conditions** for control devices.

NOTE: Additional information, other than compliance demonstration data, is required to be included in the above reports (See Chapter 13).

Using Operating Scenarios in Compliance Demonstrations

The term "operating scenario" is defined in 63.1251. In general, it is the collection of information that describes how a PMPU is operating at any one time to produce a product. It includes a description of what process equipment is used, what the emissions points are, what control standards the process is subject to, how the emissions are being controlled to the required standard, what monitoring is being conducted, as well as any other information that needs to be gathered to demonstrate compliance. A more complete list is on page 12-4. Documenting this information allows owners/operators to track all the elements that contribute to a compliance demonstration.